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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

RODRIGUEZ, CRIS LOIREN

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 05/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/826,207

Applicant(s)

DEVONEC, MARIAN

Examiner

Cris L. Rodriguez

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-128 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-88 and 90-128 is/are rejected.
- 7) ☒ Claim(s) 89 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see amendment, filed February 12, 2003, with respect to the rejection(s) of claim(s), have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Wolff et al.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 125-128 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 125 is indefinite because it is not clear what applicant intends to say between the second and third paragraph with respect to the active element and the passive retaining means in relation with the sphincter.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. **Claims 21-35, 41-46, 48-71, 77-83, and 90-124** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zilber (US 5,059,169) in view of Wolff et al (US 5,545,208).

Zilber discloses a prostatic stent, for obstruction due to prostate gland enlargement, having a non-biodegradable element (figs. 1-5) to be retained in the prostatic portion, and a withdrawal thread 22. Figure 1-2 shows a texturized fabric outer layer 20. However, Zilber fails to disclose a cytorreduction agent positioned along the element 10,30.

Wolff teaches a stent that can be used to treat the prostate gland due to chronic closure. The stent contains a cytorreductive agent such as an antimitotic agent (Col. 5 lines 56-64). Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use Wolff's cytorreductive drugs onto Zilber's prostatic stent. Doing so would have locally treated the obstruction caused by the prostate enlargement, and inhibited its growth.

6. **Claims 38, and 74** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zilber in view of Wolff et al, and further in view of Silvestrini (US 5,234,456).

Zilber/Wolff discloses the invention substantially as claimed. However, Zilber/Wolff fails to disclose that the covering substrate is hydrophilic and expandable.

Silvestrini teaches a hydrophilic stent, to be used in the urethral and ureteral ducts (col. 1, lines 56-58) that can carry drugs to be released once inserted. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use Silvestrini's hydrophilic material into Zilber/Wolff's stent. Doing so would have expanded the urethra's lumen more once in contact with the biological fluids.

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7. **Claims 36, 37, 39, 40, 72, 73, 75, and 76** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zilber in view of Wolff et al, and further in view of Yamamoto et al (US 4,676,782).

Zilber/Wolff discloses the invention substantially as claimed. However, Zilber/Wolff fails to disclose the internal core being off-centered in relation to one another, the substrate is expandable and is radially inscribed within the outer surface of the element, a sheath made of a synthetic foam, and the substrate having a plurality of channels.

Yamamoto teaches a sleeve-like tissue interface device, (figs. 4b, 5, 6a-6d), having the internal core off-centered in relation to one another, the substrate being expandable and is radially inscribed within the outer surface of the element, a sheath made of a synthetic foam, and the substrate having a plurality of channels. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Zilber/Wolff's stent with Yamamoto's devices configurations. Doing so would have provided alternate embodiments for draining body fluids, and expanding the prostatic area with such configurations.

Allowable Subject Matter

8. Claim ~~80~~^{47, 84-89} is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Claims 125-128 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

April 28, 2003



Cris L. Rodriguez
Examiner
Art Unit 3763



BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700